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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,888	06/29/2001	Tom A. Grigliatti	4810-59380	3346

7590

07/29/2003

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

9

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/896,888

Applicant(s)

GRIGLIATTI ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17,23 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17,23 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 2,3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This Office action is in response to the Preliminary amendment filed by applicants on 4/4/02.

Claims 1-17, 23, and 27-29 are pending in the case.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-17, 23, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112 first paragraph "Written Description" published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). The claims are drawn to shuttle vectors wherein a selectable marker coding sequence is present, and said selectable marker confers a selectable phenotype on insect and bacterial cells transformed with the shuttle vector. The disclosure is not deemed to be descriptive of

the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the encompassed vectors based on the teachings of the specification. The vectors described in the specification are limited to those containing the zeomycin resistance gene for conferring a selectable phenotype in both prokaryotic and insect cells. While the specification provides some general information on the use of antibiotic resistance genes in insect cell vectors, there is no structure-function analysis of the disclosed zeomycin resistance conferring protein to provide guidance on the selection of other resistance marker genes encoding proteins which may function in insect and prokaryotic cells. Therefore, the specification does not describe the claimed insect-prokaryotic shuttle vectors containing a selectable marker conferring a selectable phenotype in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the claimed shuttle vectors at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Claims 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112 first paragraph "Written Description" published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claims 27-29 are drawn to shuttle vectors containing an insect promoter comprising : an IE2B element having at least 95% sequence identity to SEQ ID NO: 10 (claim 27), a sequence with at least 95% sequence identity to SEQ ID NO:1 from bp 351-527 (claim 28), or a sequence with at least 95% sequence identity to SEQ ID NO 1 (claim 29) wherein the insect promoter is a functional promoter. These claims are genus claims in terms of encompassing numerous variants which have 95% homology to a recited sequence, which remain functional as a promoter. The specification teaches shuttle vectors using an insect promoter having exact homology to the above recited sequences. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the encompassed promoters based on the teachings of the specification. The specification does not provide any structure-function analysis of the disclosed promoter sequences analyzing which alterations may result in functional promoters. Therefore, the specification does not describe the claimed insect-prokaryotic shuttle vectors containing an insect promoter having 95% homology to the recited sequences in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the claimed shuttle vectors at the time of filing the present application. Thus, the written description requirement has not been satisfied.

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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July 24, 2003

  
TERRY MCKELVEY  
PRIMARY EXAMINER